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Via ECF

Hon. Madeline Cox Arleo
Martin Luther King, Jr. Federal Building & U.S. Courthouse
U.S. District Court of New Jersey
50 Walnut Street
Newark, New Jersey 07101

Re: *Castro v. Sanofi Pasteur Inc.*, 2:11-cv-07178 (MCA) (MAH)

Dear Judge Arleo:

Consistent with the Court's suggestion during the July 9th teleconference, we write in advance of the upcoming *Daubert* hearing to assert Sanofi's objections to the following exhibits identified by plaintiffs: PX 1, 14-16, 23-28, 34, 36, 42, 1001, 1003, 1004, 1006, 1009, 1010, 1018, 1019, 1022, 1031, 1034-1036, and 1038 (the "Challenged Exhibits").¹

As the Court made clear during the telephone conference, the upcoming hearing is a *Daubert* hearing, and should be limited to *Daubert* issues. Those issues are generally limited to the "qualification, reliability, and fit" of proffered expert opinion. *See Schneider v. Fried*, 320 F.3d 396, 404 (3rd Cir. 2003). Here, they are limited to those aspects of Elhauge's work that Sanofi has specifically challenged, as plaintiffs acknowledged shortly after the last conference. *See* Pl. Ltr. (ECF 376) at 2 (proposing format centered around "those aspects of [Elhauge's] analyses, methods, and findings **to which Sanofi has objected.**"); *id.* ("As the Court admonished the parties, neither class certification nor Sanofi's *Daubert* motion requires or permits a 'mini-trial' on the merits of the case.").

¹ Sanofi also renews its objections to Elhauge's supplemental opinions as set forth in its Motion to Strike. ECF 364. This includes Elhauge's opinions concerning his second, third, and fourth Menveo share regressions, E.2 ¶¶ 41-44; E.3 ¶¶ 100-102; Elhauge's first and second "falsification tests," E.2 ¶¶ 62-63; E.3 ¶ 144; Elhauge's price dispersion analysis, E.2 ¶¶ 179-80; Elhauge's second, third, and fourth marginal cost estimates and associated overcharge simulations, E.2 ¶¶ 282-86; Elhauge's additional eleven new analyses contained in his second report identified in footnote 4, E.2 ¶¶ 37, 87, 111-12, 122-23, 124, 151-54, 165, 184, 236-37, 284, 322; Elhauge's market expansion (silent epidemic) theory and calculations, and the associated forward-looking costs analysis, E.3 ¶¶ 75-85; Elhauge's vaccine industry profit analysis based on the anonymous skepticalraptor.com blog, E.3 ¶ 199 & n.278; and Elhauge's fourth report/declaration, P. Ex. 55. *See* ECF 364 at 2.



Elhauge's *methods* are on trial at the *Daubert* hearing; the merits of plaintiffs' case, and even the merits of their motion for class certification, are not. In their class motion, plaintiffs asserted two separate avenues to class certification: (1) Elhauge's economic analyses, and (2) documentary evidence. ECF 310. The second is simply not relevant to the *Daubert* hearing. Plaintiffs' burden here is to establish the admissibility of Elhauge's opinions – to show they are based on sufficient facts or data, are the product of reliable principles and methods, and that those methods have been applied to the facts of the case. SD Br. at 3 (ECF 338). The hearing should focus on those precise issues.

In its *Daubert* motion, Sanofi identified specific flaws in Elhauge's methodology that render them unreliable and inadmissible under Rule 702. Specifically, Sanofi challenged the reliability of (i) Elhauge's incentive modification theory; (ii) his assumption of no price discrimination; (iii) his Menveo Share Regressions; (iv) his failure to employ a control group; (v) his selection of, and failure to empirically validate or calibrate, his Bertrand price war simulation; (vi) his assumption of no coordinated interaction; (vii) his assumption that the VFC disappears in the but for world; (viii) his assumption that there is a silent epidemic of unvaccinated adolescents in the actual world; (ix) his list price reduction assumption; and (x) his entry analysis. These are the relevant issues for the *Daubert* hearing.

None of Sanofi's challenges go to the *existence* of what Elhauge has pejoratively termed the "Menactra Bundled Loyalty Condition," or "MBLC." Nor do any of Sanofi's challenges go to the enforcement practices – by Sanofi, a PBG, or otherwise – of the "MBLC." While Sanofi believes plaintiffs' factual allegations concerning so-called "penalties" are false, that dispute is irrelevant for purposes of Sanofi's *Daubert* motion. ***For purposes of this motion (only)***, the Court may accept plaintiffs' characterization of its discounts as "penalties" and their assertion that *some* unspecified contract customers chose not to switch to Menveo because they feared a risk of termination.

While the Challenged Exhibits may touch on some of these "facts," they have nothing to do with the reliability of Elhauge's methods. Documents that discuss Sanofi's contract enforcement cannot render an otherwise flawed statistical analysis, simulation, or economic theory reliable, especially where, as here, the documents do not speak to the precise flaws Sanofi has identified. The Challenged Exhibits' irrelevance to the *Daubert* issues is evidenced by the fact that Elhauge never cited (let alone "relied on") many of plaintiffs' marked exhibits in the 500-plus pages of his reports. *See* Attachment A (identifying Challenged Exhibits not cited by Elhauge, including PX 1, 14-16, 22, 23, 27, 34, 36, 42, 1004, 1010, 1022, 1031, 1038). And those he did cite were for different issues or different analyses than those raised by Sanofi's *Daubert* motion. *See* Attachment A (identifying PX 24-26, 28, 1001, 1003, 1006, 1009, 1018, 1019, 1034-1036).²

Sanofi is making a good faith effort to reduce the burden on the Court and on plaintiffs by limiting its presentation to the issues at hand. There are, of course, many other issues Sanofi

² In asserting objections to plaintiffs' pre-marked exhibits, Sanofi assumes they are proffered for the reasons cited in Elhauge's reports or plaintiffs' briefs. If plaintiffs intend to use the exhibits for other purposes, Sanofi reserves any additional objections to those uses. Sanofi also reserves the right to object to any of plaintiffs' pre-marked exhibits other than the Challenged Exhibits based on plaintiffs' actual use of such documents at the hearing.



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would present to the Court in another context, relating to class (only), foreclosure or the lack thereof, the origins of this suit, or the truth about its “compliance” measures, by way of example. But the *Daubert* hearing is not the right forum. Plaintiffs should be held to the same standard.

Respectfully submitted,

/s/

Wanda L. Ellert and Colin R. Kass